list

ATTACHMENT I

Evaluation of Modeled Uptake Assumptions and Transfer Factors Used in the Agricultural Products Consumption Risk Assessment

1.0 Introduction

In its Human Health Risk Assessment (HHRA), EPA has evaluated potential risks associated with the consumption of agricultural food items raised on floodplain soil or feed silage grown on these soils. These agricultural food items include dairy products (milk and cheese), beef, chicken, and eggs.

The exposure to PCBs and other chemicals of potential concern (COPCs) in floodplain soil via consumption of agricultural products is dependent on the efficiency of the transfer of soil-bound compounds into the food product ultimately consumed by people in the Housatonic River area. The primary human exposure pathway identified and evaluated in the HHRA is essentially a three- or four-level food web:

Soil → animal → consumer

Soil → plants (pasture or silage) → animal → consumer

Since these are not direct exposure pathways, the evaluation of the transfer of COPCs from soil to humans had to include a consideration of the movement of the chemicals through one or two levels, and this movement had to be quantitatively evaluated as part of estimating exposure and ultimately risk.

In the quantitative assessment, the HHRA generally does not rely on empirical data collected from the site to determine the efficiency of the movement of PCBs through this food web. Rather, the assessment relies on limited analytical data to establish certain relationships (e.g., transfer factors) for predictive purposes and uses mathematical models to derive exposure and dose estimates for hypothetical exposure scenarios. Since the derived doses were estimated or modeled, there is an inherent level of uncertainty incorporated into the risk calculations in addition to the uncertainty typically associated with the risk assessment process. A high degree of uncertainty is associated with the use of some of the predictive tools, and the dose and risk estimates produced are consequently unreliable. The primary sources of the uncertainty in the exposure models used in the HHRA are described in the following sections.

These uncertainties could be reduced by the collection of current PCB data on the agricultural food items themselves (e.g., milk, beef, poultry, eggs). Alternatively, in the absence of such direct data, some of the uncertainties could be reduced by collecting additional site-specific data on intermediate items in the food web (e.g., grass with co-located soil data). In other cases, the uncertainties cannot be reduced simply by collecting such additional data, and consideration should thus be given to either eliminating these portions of the assessment or limiting their discussion to the Uncertainty Analysis of the report.

2.0 Transfer of COPCs from Soil to Plants

The uncertainties involved in the transfer of COPCs from soil to plants involve both the prediction of COPC concentrations in the soil and the models used to predict uptake of those COPCs from the soil to the plants. These are discussed in the following sections.

2.1 Predicted Concentrations of COPCs in Soil

While EPA and GE have collected numerous samples of floodplain soil and analyzed them for PCBs as Aroclors, the quantitative assessment is not limited to an evaluation of the potential risks associated with exposure to total PCBs (tPCBs) but also includes exposure to PCB congeners and polychlorinated dibenzo-*p*-dioxins and polychlorinated dibenzofurans (PCDDs/PCDFs). In order to accomplish these additional evaluations, a limited number of soil samples were collected and analyzed for tPCBs and concentrations of specific "dioxin-like" PCB congeners as well as PCDDs and PCDFs. Based on these results, correlations between tPCB concentrations and the concentrations of the latter COPCs were established and used as a predictive tool to convert tPCB levels into corresponding levels of PCB congeners and PCDDs/PCDFs. The results of this conversion process are provided in Tables 2 and 3 of Attachment 2 of the HHRA.

This conversion or extrapolation process used to derive hypothetical dioxin-like PCB congener and PCDD/PCDF soil concentrations from predetermined tPCB concentrations of 0.5 ppm and 2 ppm creates one of the most significant uncertainties in the Agricultural Products Consumption Risk Assessment. Other problems with this approach, such as those related to the use of the dioxin toxic equivalency TEQ methodology used to convert the predicted PCB congeners concentrations into corresponding dioxin concentrations, are described in detail in Section 6.1.1 and Attachment L of this set of comments.

A careful evaluation of the data collected from the floodplain soils reveals the uncertainty and inaccuracy associated with EPA's effort to model predicted exposure concentrations of COPCs. The limited number of additional soil samples that EPA collected and used to develop the regression models were taken from floodplain soils that contained a mean PCB concentration of 11.5 ppm. This is roughly six times higher than the highest predetermined soil concentration of 2 ppm, and more than 20 times higher than the lower hypothetical concentration of 0.5 ppm. Using the relationships developed in the HHRA resulted in predicted PCB congener and PCDD and PCDF concentrations below the associated analytical detection limits. As a result, the regression model predicted concentrations used in the quantitative risk estimates that could not be verified. For example, EPA's conversion process was used to predict that at a tPCB soil concentration of 10 ppm, the corresponding soil concentration of 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD) would be 1.6 pg/kg. Accordingly, the predicted TCDD concentration at 0.5 ppm tPCB would be 0.08 pg/kg, which is below the apparent detection limit based on the data presented in Table 1 of Attachment 2 of the HHRA.

The same is true for PCB-126, the PCB congener with the highest toxic equivalency factor and the one that accounts for 54 percent of the total TEQ (Table 3 in Attachment 2). The predicted concentration of PCB-126 at a tPCB concentration of 10 ppm is 0.83 µg/kg (ppb). At a tPCB concentration of 0.5 ppm, the predicted concentration of PCB-126 would be 0.0415 ppb. The analytical detection limit for PCB-126 for the floodplain soil samples was greater than 0.1 ppb. Thus, the concentration of the primary risk driver in terms of dioxin equivalency used in the assessment of risk associated with the consumption of agricultural products could not be verified, as it was below the analytical method's detect limit. As discussed in the following sections, the substantial uncertainty introduced into the assessment process by this methodology is magnified with each successive modeling step. As a result of this multiplicative uncertainty, the risk estimates for dioxin-like compounds are so uncertain as to be unreliable.

In consideration of these substantial uncertainties, combined with the questionable scientific validity of the TEQ approach itself (as discussed in Section 6.1.1 and Attachment L), GE recommends that this approach be dropped and that the HHRA be revised to limit the assessment of the Agricultural Products Consumption pathway to tPCBs.

2.2 Transfer of COPCs from Soil to Plant Tissue

For dairy and beef cattle, the primary exposure pathway for COPCs in soil is the ingestion of pasture hay and grass and corn silage grown in the floodplain soils. In order to quantify the movement of COPCs from soil into agricultural products, estimates of the transfer efficiency were developed. Again, the HHRA did not rely upon empirical data collected from relevant areas of the Housatonic River floodplain to specifically determine the extent of this transfer, but instead resorted to another modeling technique to predict the movement of COPCs from the soil to the plant material. The steps required to complete the modeling involved numerous assumptions that were based on only limited data, or in some cases, were actually contrary to site-specific data.

2.2.1 Soil-to-grass transfer factors for tPCBs and PCB congeners

Soil-to-grass transfer factors for tPCBs and PCB congeners were developed based on a single sampling event and only a few soil and grass samples. These single-event sampling data were used to estimate long-term concentrations in the pasture hay and grass silage consumed by the farm animals. It is likely that this approach resulted in biased transfer factors that may not be representative of actual transfer of these compounds.

The grass sampling data provide only a snapshot of environmental conditions at a particular point in time. The HHRA correctly notes that environmental conditions may "influence" PCB concentrations in (or on) plants (Vol. V, p. 4-21). Because PCB congeners have relatively low volatility, the deposition of the particle phase may be the most important transfer route. This is evident as there was a "shift toward less volatile congeners in grass compared with soil" (Vol. V, p. 4-23).

Meteorological conditions may have an important influence on the amount of PCBs or PCDDs/PCDFs that would be harvested or consumed (via grazing) along with the plant matter. The HHRA acknowledges that field studies are preferable to laboratory investigations because "field studies account for losses due to wind, rain and photolysis" (Vol. V, p. 4-22). The one-time collection of plant material did not, however, account for these variables, and may therefore have biased the results. According to the HHRA, while the time the samples were collected coincided with the period when hay harvesting typically occurs, it did *not* account for several environmental conditions that likely maximized the PCB levels in grass. The samples were

collected: 1) during the warmer months of the year; 2) during a period with no heavy rain; 3) from areas that adjacent to the river channel where recent inundation with floodwaters was evident; and 4) from areas with high levels of tPCBs. These conditions would tend to exaggerate the estimated long-term transfer from soil to grass. In fact, the HHRA speculates that both the time of year and location (adjacent to the river channel with evidence of recent floodwater inundation) may have maximized grass "exposure" (Vol. V. p. 2-6). Unfortunately, the magnitude of this bias cannot be determined with the currently available data.

Limited sampling from pre-selected locations under particular conditions (hot and no rain) all maximized the estimated movement of COPCs from soil to plants. Published data support the conclusion that the sampling conditions likely resulted in an overestimation of the transfer efficiency. Chaney et al. (1996) estimated that a transfer factor of 0.001 (µg tPCB/g crop dry wt per µg tPCB/g soil dry wt) is generally appropriate for forage crops, while a transfer factor of 0.0001 is appropriate for grain crops. Comparable values developed in the HHRA for tPCBs in grass and corn are 0.04 and 0.002, respectively (Vol. V, Table 4-5), which are more than an order of magnitude higher than those proposed by Chaney et al. Although the values reported by Chaney et al. are not from the Housatonic River floodplain, they do provide a point of reference for the magnitude of PCB transfer to plant material. Given that these transfer factors were used to directly estimate intake of COPCs by the animals and ultimately exposures to humans, this overestimation likely had a significant impact on the estimates of risks and hazards from this pathway.

The data from the single sampling event are too limited to derive transfer factors that can be used to confidently estimate exposures to agricultural animals. Having precise transfer factors is particularly critical since ingestion of plant matter, as opposed to soil, is the primary route of exposure for beef and dairy cattle. Collection of additional data from areas representing different reaches of the river floodplain and during events representative of various weather conditions would facilitate the construct of reasonable and accurate estimates of transfer efficiencies from soil to plants. GE recommends that these data be collected before this component of the exposure model is used to quantify risks.

2.2.2 Assumption of a linear relationship between soil concentrations and predicted plant concentrations

An explicit assumption in the HHRA is a linear relationship between soil concentrations of COPCs and related predicted plant concentrations (Vol. V, p. 4-23), even though the data for tPCBs (r = 0.494) and some PCB congeners do not support this assumption. In fact, data presented in the HHRA show that some of the congeners had a negative correlation (as the PCB congener concentration in soil increased, the concentration in grass decreased). This is true for several "dioxin-like" PCB congeners including PCB-77, PCB-105, PCB-156, and PCB-169 (Vol. V, Figure 4-4a). Thus, the available site-specific data do not support the assumption of a linear relationship to estimate plant concentrations of PCB congeners. The lack of a linear relationship for these congeners may be due to the fact that the relative proportion of the various congeners within the floodplain is not constant and that this variability is reflected in the sampling results for soil and grass, or else the database may be too small to demonstrate a linear relationship. In either case, additional site-specific sampling of floodplain soil and co-located grass would reduce the uncertainty and could be used to determine the veracity and utility of the assumption. Until these additional data are collected, the risk estimates derived from the predicted concentrations cannot be considered reasonable.

2.2.3 Soil-to-corn transfer factors

In order to model exposures to agricultural animals via consumption of corn silage, EPA developed transfer factors for both tPCBs and PCB congeners from soil to corn silage (see Vol. V, p. 4-24). For tPCBs, however, the sampling data showed no detected tPCBs in corn ears, and the 10 corn stalk samples from the floodplain showed either non-detected tPCBs (5 samples) or estimated values (5 samples with J qualifiers) (Vol. V, Table 2-4). In these circumstances, EPA elected to base the soil-to-corn transfer factor for tPCBs only on the 5 corn stalk samples with estimated values. The HHRA recognizes that this method "likely overestimates PCB transfer to corn" (Vol. V, p. 4-24). Moreover, given the absence of detected tPCBs in corn ears and the mix of only non-detect and estimated values for corn stalks, this transfer factor is highly uncertain and the magnitude of its overestimate cannot be determined. This uncertainty is particularly significant since corn silage was considered the major portion of the diet (and the only source of soil-associated PCBs) for dairy cows and nearly half of the diet and source of tPCBs for beef cattle. In fact, use of the corn sampling results to derive transfer factors appears to be inconsistent with EPA guidance, which indicates that where, as in this

case, there are *no* samples in a data set with unqualified measurable concentrations, the data set should not be used for quantitative risk assessment (EPA, 1989, p. 5-11).

For PCB congeners, there are no data at all on such congeners in corn, and hence the HHRA relied on modifications to the PCB congener-specific soil-to-grass transfer factors, which as noted in Section 2.2.1, have a high degree of uncertainty. Since EPA's modeled soil-to-grass transfer factors for tPCBs were higher than the estimated soil-to-corn transfer factors developed for tPCBs, the estimated PCB congener soil-to-grass transfer factors had to be modified to a similar degree. To do so, the PCB congener "soil-to-corn transfer factors were estimated by multiplying [PCB congener] soil-to-grass transfer factors by the ratio of the tPCB soil-to-corn transfer factor to the tPCB soil-to-grass transfer factor" (Vol. V, p. 4-24). Of all these factors, only the tPCB soil-to-grass transfer factors were based on actual measurable site data and those data were very limited. In consequence, the level of uncertainty associated with the resulting PCB congener soil-to-corn transfer factors renders those factors unusable.

In short, the corn silage route of exposure for agricultural animals (and ultimately humans) was assumed to be complete even though there are no site data to verify or allow a reliable quantitative estimate of the translocation of COPCs from the soil into the corn silage that cows eat. As such, the results of this modeling cannot be considered reliable. In fact, other reports in the scientific literature indicate that PCB s are not translocated from soil to corn (O'Connor et al., 1990; Webber et al., 1994; Gan and Berthouex, 1994). In these circumstances, GE believes that corn silage as a route of exposure should be eliminated from the risk assessment.

3.0 Bioaccumulation into Beef and Dairy Cattle and Poultry

In addition to predicting the concentrations of COPCs in the grass and corn silage consumed by agricultural animals, the HHRA had to estimate the concentrations of those COPCs in the animal products consumed by people. In the absence of site-specific data on those animal products, determining tissue concentrations of the COPCs required the use of a model. The HHRA incorporated numerous assumptions into this bioaccumulation model in order to translate the prescribed floodplain soil tPCB concentrations (2 ppm and 0.5 ppm) into COPC tissue burdens. However, certain of the key assumptions incorporated in the model are unsupported or overestimated, as discussed below.

3.1 Assumption of Steady State

An important assumption applied in the bioaccumulation model is that the dairy and beef cattle and chickens are at steady state with COPCs in floodplain soil – i.e., that the COPC intake rate by the animal is constant and that it equals the rate of elimination of these compounds. This assumption requires that concentrations in all of the soil, grass, and corn silage are constant and reflect soil concentrations of either 0.5 ppm or 2 ppm tPCBs. Thus, there can be no significant temporal or spatial variations in tPCB concentrations in farm soils, grass, or corn. Likewise, concentrations of other COPCs (PCB congeners, PCDDs and PCDFs) associated with these two predetermined concentrations of tPCBs, which were estimated using the modeling methods discussed previously, are assumed to be constant. However, under conditions existing at the Housatonic River floodplain, the requirement of steady-state conditions could most likely not be satisfied. Assuming these conditions exist and then developing tissue concentrations based on this assumption can only result in an overestimation of the level of COPCs accumulating into agricultural products.

The animals being considered as a food source would not actually be at steady state because the levels of "contamination" in their environment (either via grazing or from provided feed) are highly variable. Site data from floodplain soils clearly illustrate the variability inherent in the COPC distribution. PCB concentrations in floodplain soils may, for practical purposes, be temporally stable (i.e., no change over time). However, the basic assumption of steady state would not be valid because the animals will graze in different areas at different times (most of the time outside the 1 ppm isopleth), or the source of supplied food (grass roughage or corn silage) will be derived at different times from different sources (most of it from outside the 1 ppm isopleth). To assume that the concentrations of COPCs in grass or corn silage will not vary from day to day and to ignore the likelihood that there will be days when the animal will not ingest COPCs is unrealistic and not supported by either site-specific data or published scientific studies.

The HHRA explains how its risk estimates, which are based on the assumption that 100 percent of the pasture and cultivation areas are within the 1 ppm isopleth, can be applied to "actual exposure conditions" where all of the animals' food source does not originate from within the 1 ppm isopleth (Vol. V, pp. 4-1 - 4-2). It suggests, for example, that the results obtaining by assuming that 100 percent of the cultivated land has a soil concentration of 0.5 ppm would likewise apply to a property that has 10 percent of the cultivated land at 5 ppm and 90 percent

with no PCBs. While mathematically this approach has merit, assuming that only a fraction of the floodplain is used for pasturing or cultivated for corn does not address the issue of non-steady-state modeling conditions. Under the example scenario provided in the HHRA, steady-state conditions would not exist, and thus the models explicitly assuming this condition would be inappropriate for use. In fact, the suggestion in the HHRA that 100 percent cultivated land at 0.5 ppm is equivalent to 10 percent at 5 ppm and 90 percent with no PCBs is not correct in terms of dictating body burdens because it does not take account of kinetic parameters. This can be illustrated by considering a hypothetical condition where the animal receives feed material associated with 5 ppm soil on day 1, then consumes material without any PCBs for the following 9 days, and then gets "dosed" with 5 ppm-associated feed again on day 11. This would not result in the same steady-state PCB body burdens (and milk concentrations) as those resulting from a constant exposure (and dose) of 0.5 ppm-related feed.

One of the primary references identified as a source of the accumulation models developed in the HHRA (Thomas et al., 1999) highlights the difficulty in achieving the explicit assumption of steady-state conditions, even after 15 weeks of constant feeding under controlled conditions. The authors stated: "True steady-state conditions were not attained at any time, and therefore models which assume steady-state conditions to predict milk and meat concentrations should be used with care."

Since the grass and corn silage that these animals eat do not all grow in impacted soil in the floodplain, and since the COPCs in the floodplain are not at a constant concentration, a non-steady-state approach to estimating bioaccumulation should be incorporated into the HHRA. This would require consideration not only of variability in intakes, but also of the changes in the distribution of the chemicals within the animal due to growth and variability of elimination associated with lactation.

At the very least, if a non-steady-model is not used, EPA should incorporate a factor into the HHRA that accounts for the limited contribution that the floodplain soils have to the diet and adjust the intakes accordingly. For example, in sensitivity analysis, the HHRA uses a factor of 15 percent based on the approximate percentage of farm cultivation areas in Reach 5 (Vol. V, p. 5-10). Under this approach, while the assumption of steady-state conditions would still result in an overestimate of accumulation, this impact would be minimized to some degree by reducing the contribution of COPCs in floodplain soils to the overall diet.

3.2 Assumption of Complete Absorption of COPCs in the Ingested Material

The HHRA contains the explicit assumption that the bioavailability of the COPCs in ingested material (soil, grass, corn silage) is 100 percent, as the "factor for reduced bioavailability in soil" in the exposure equation was set at 1 (Vol. V, p. 4-9). That is, there is no consideration of the impact of soil organic matter on COPC absorption into the animals, even though available data suggest that failure to consider this fact could lead to a two-fold overestimation of absorption. For other ingested material, the assumption of 100 percent bioavailability is implicit, as the factor for adjusting "reduced bioavailability" was not included in the equation for determining COPC concentrations in animal tissue from corn silage or grass. In either instance, assuming that all ingested COPCs are absorbed is inconsistent with available scientific information.

Ruby et al. (2002) reported that the bioaccessibility (a surrogate for oral bioavailability) of low concentrations of PCDDs and PCDFs ranged from 19 percent to 34 percent. Similar results were reported by Hack and Selenka (1996) for PCBs in a "standardized gastro-intestinal model." The HHRA itself contains information that contradicts the assumption of 100 percent bioavailability. Table 4-4b of Volume V indicates that, based on Thomas et al. (1999), the percentage of PCB congeners absorbed from feed material (silage and concentrate) ranged from 44 percent to 84 percent. Bioavailability from soil is likely to be further reduced as ATSDR (2000) reported that adsorption of PCBs onto soil has been shown to reduce their oral bioavailability to a greater degree than the matrix effect from food matter.

While no data on specific "dioxin-like" congeners were provided by Thomas et al., percent absorption results from structurally similar congeners can be used to shed some light on the potential impact of the assumption of 100 percent bioavailability on animal body burdens. PCB-101, a pentachloro-PCB (like PCB-126), with a log K_{ow} similar to PCB-126, had an absorption value of 65 percent (Table 4-4b). Likewise, the hexachloro-substituted PCB congeners (e.g., 138, 149, 151, and 153), which are structurally similar to the dioxin-like PCB-156 and PCB-169, had absorption values of roughly 50 percent. Not accounting for this reduction in bioavailability in the estimated the internal dose in cattle and chickens significantly overestimates the steady-state body burdens of the animals.

Failure to consider the reduction in the internal dose in cattle and chickens also significantly impacts the human health risk calculations. Since that factor results in an overestimate of the

estimated COPC concentrations in the consumed animal products (i.e., eggs, chicken, milk, and beef), the risks associated with these exposures are proportionally overestimated.

Factors that reflect percent bioavailability can be derived from information in the literature for PCBs, the important PCB congeners, and PCDDs/PCDFs. For example, Table 4-4b of Vol. V contains "predicted absorption" values for the dioxin-like PCB congeners, developed from the available scientific literature. Similar values could be developed for tPCBs (e.g., 65 percent based on Hack and Selenka, 1996) and for PCDDs/PCDFs (e.g., 35 percent based on Ruby et al., 2002). Such factors should be incorporated in the exposure equations for human ingestion of animal products to prevent a significant overestimation of dose, and consequently risk.

3.2.3 Bioconcentration Factors Used To Predict COPCs in Milk and Body Fat

Once the COPCs have been ingested by the animal, one final calculation needed to be completed in order to estimate the concentration of the chemicals in the tissue that would be consumed by the local population. This estimation was accomplished with the incorporation of a bioconcentration factor (BCF), which is used to quantify the partitioning of the absorbed COPCs into the animal tissues. While no appropriate studies were identified in the HHRA for deriving a BCF from diet to tissue, studies were identified that characterize the transfer of PCBs from diet to milk. The HHRA adopted BCFs for tPCBs and PCB congeners that were the maximum reported or upper-bound values for milk fat in the literature (Vol. V, pp. 4-14 - 4-18, 5-11). In order to estimate tissue concentrations, the HHRA assumed that the BCFs in body fat would approximate the BCFs for the milk of dairy cows (Vol. V, p. 4-7). Thus, the selection of the maximum BCF for milk fat impacted not only the estimates of PCBs in milk but also in beef.

Additionally, the HHRA contains the assumption that relatively stable concentrations are attained in body fat if the concentration in the diet is constant during growth (a problematic assumption addressed in Section 3.1). This assumption is not supported by the scientific literature. In a paper cited in the HHRA, Thomas et al. (1999) stated: "It was found that concentrations in milk dropped by an average of 25 percent through lactation, while PCB intake rose as the cows voluntarily ate more silage later in lactation." Since it is likely that neither PCB concentrations in food nor fat levels in milk changed during this same period, these data indicate that the BCF for milk fat would have declined over the study period (15 weeks). Thus, this study contradicts the assumption that stable concentrations would be attained in body fat.

The justification given for selecting the maximum or upper-bound BCFs for the PCB mixtures and congeners is the limited amount of data in the literature (Vol. V, p. 5-11). The HHRA acknowledges, however, that the available published data suggest that BCFs for both PCB mixtures and PCB congeners might be significantly lower, and it provides a sensitivity analysis with those lower values (*ibid.*). Since many of the other model parameters and exposure variables that EPA selected provide exposure estimates on the high end of the range or that tend to overestimate exposure, as discussed above, it would be reasonable and consistent with EPA guidance (EPA, 1992) to incorporate the other published BCF values used in the sensitivity analysis into the main risk calculations, and GE believes that EPA should do so.

4.0 References

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